

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/007287	International filing date (day/month/year) 01.07.2004	Priority date (day/month/year) 29.07.2003	
International Patent Classification (IPC) or national classification and IPC A23C9/152, A23C9/123, A23L1/30, A23D7/01			
Applicant UNILEVER N.V.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 17.12.2004		Date of completion of this report 08.07.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Rooney, K Telephone No. +31 70 340- 3931 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/007287

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-11 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/007287

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement
- | | | |
|-------------------------------|-------------|-------|
| Novelty (N) | Yes: Claims | 10-11 |
| | No: Claims | 1-9 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-11 |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
| | No: Claims | |
2. Citations and explanations (Rule 70.7):
- see separate sheet

Re Item V.

1 The following documents are referred to in this communication:

- D1: WO 00/61771 A (MONSANTO CO) 19 October 2000 (2000-10-19)
- D2: ATTA, M. B., AND IMAIZUMI, K.: "Some characteristics of crude oil extracted from roselle (*Hibiscus sabdariffa* L.) seeds cultivated in Egypt" JOURNAL OF OLEO SCIENCE, vol. 51, no. 7, 2002, pages 457-461, XP008025023 JAPAN OIL CHEMISTS SOCIETY, TOKYO, JP ISSN: 1345-8957
- D3: VENKATRAMESH, M., KARUNANANDAA, B., SUN, B., GUNTER, C. A., BODDUPALLI, S. AND KISHORE, G. M.: "Expression of a *Streptomyces* 3-hydroxysteroid oxidase gene in oilseeds for converting phytosterols to phytosterols" PHYTOCHEMISTRY., vol. 62, 2003, pages 39-46, XP002262565 PERGAMON PRESS., GB ISSN: 0031-9422
- D4: SANDERS, D. J., MINTER, H. J., HOWES, D., AND HEPBURN, P. A.: "the safety evaluation of phytosterol esters. Part 6. The comparative absorption and tissue distribution of phytosterols in the rat." FOOD AND CHEMICAL TOXICOLOGY., vol. 38, 2000, pages 485-491, XP002262566 ISSN: 0278-6915
- D5: WO 98/01759 A (FORBES MEDI TECH INC) 15 January 1998 (1998-01-15)
- D6: US 2003/134833 A1 (WESTER INGMAR ET AL) 17 July 2003 (2003-07-17)
- D7: NORMEN, L., ET AL.: "The phytosterol content of some cereal foods commonly consumed in Sweden and in the Netherlands" JOURNAL OF FOOD COMPOSITION AND ANALYSIS., vol. 15, 2002, pages 693-704, XP002301893 GBACADEMIC PRESS, LONDON.
- D8: HOWELL, T. J., ET AL.: "Phytosterols partially explain differences in cholesterol metabolism caused by corn or olive oil feeding" JOURNAL OF LIPID RESEARCH, vol. 39, 1998, pages 892-900, XP002301894 USBETHESDA, MD

2 Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 9 is not new in the sense of Article 33(2) PCT.

The document D1 discloses vegetable food products (plants which implicitly comprise

an aqueous phase) having 3.5 (7.6wt%) μ grams/g beta sitostanol (stigmastanol) and 42.2 (92.2 wt%) μ grams/g beta-sitosterol (see D1: table 8 and claims 49 and 63).

The document D2 discloses water containing food products such as jams and juices which contain 94.5% beta sitosterol and 5.5% beta sitostanol based on the total weight of both components (see D2: page 457, column 2 and table 4).

The document D3 discloses plant seeds which comprises beta sitosterol and a small amount of beta sitostanol which are suitable for reducing the absorption of beta sitosterol in the blood (see D3: the whole document).

The document D4 discloses compositions comprising beta sitosterol and a small amount of beta sitostanol which are suitable for reducing the absorption of beta sitosterol in the blood (see D4: page 486, column 2).

The document D5 discloses edible compositions comprising beta sitosterol and a small amount of beta sitostanol which are suitable for reducing the absorption of beta sitosterol in the blood (see D5: page 24, 25).

The document D6 discloses food compositions containing beta sitosterol and beta sitostanol (from sources typically having less of the stanol than sterol e.g. rapeseed etc.) which are suitable for reducing the absorption of beta sitosterol in the blood (see D6: the whole document).

The document D7 discloses food compositions containing beta sitosterol and less beta sitostanol which are suitable for reducing the absorption of beta sitosterol in the blood (see D7: example 1).

3 Inventivity

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 10 and 11 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D7 discloses methods of preparing formulations for reducing the uptake of beta sitosterol in blood which consists of using a composition made up of a mixture of beta sitosterol and beta sitostanol (see D7: column 6, paragraph 1 and example 1).

The subject-matter of claim 10 differs from the composition described in D7 merely in so far as the components of the mixture have been quantified. However, it is unclear whether or not the composition of claim 10 is the same as that of D7. Therefore it appears that the subject-matter of claim 10 is a selection of a range of values from those predescribed in the prior art, without any inventive activity.

The document D8 discloses the phytosterol content of diets where beta sitosterol is found at 62% and beta sitostanol at 4%. The consumption of these diets was linked to changes in serum lipid concentration (see D8: abstract and page 694, paragraph 1). The document D9 (referred to by D8) discloses that the serum triglycerides concentration can be reduced by the use of phytosterol mixtures (see D9: figure 1 and page 897). It seems that when the teaching of the documents D8 and D9 are taken together, the subject-matter of claim 11 appears to be obvious to those skilled in the art and hence un inventive.

4 Dependent Claims

Dependent claims 2-8 have been disclosed in their present form in the cited prior art and therefore are not novel.